

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO:

CIVIL ACTION: 01-CV-12257-PBS

ALL CLASS ACTIONS

Judge Patti B. Saris

**RESPONSE OF CLASS PLAINTIFFS TO STATEMENT OF UNDISPUTED FACTS IN
SUPPORT OF TRACK 1 DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Class Plaintiffs, by their counsel, hereby respond to the Statement of Undisputed Facts in Support of the Track 1 Defendants' Motion for Summary Judgment and where necessary counter designate undisputed facts in opposition to Defendants' motion.

1. Plaintiffs admit that in 1969, some 20 plus years before events at issue in this case, the report referred to was issued.

2. Admitted that in 1974, some 20 years prior to the start of the events at issue, this report was issued. However, Plaintiffs dispute the relevancy of the statement that AWP was "in excess of actual acquisition cost to the retail pharmacist."

3. Plaintiffs do not dispute that in 1975, some 20 years prior to many of the events at issue, the statement appeared in the Federal Register. Plaintiffs dispute the relevancy of this statement and counter designate as undisputed the statement in this section of the Register that

“actual acquisition cost is difficult to determine” and that comments were received that actual acquisition cost be defined as the average wholesale price (Ex. 3 at 32293).

4. Plaintiffs admit that Ex. 4 reported that “AWPs were 15 to 18 percent higher than acquisition costs.” The document also notes and plaintiffs assert as an undisputed fact the statement “that programs using EAC (estimated acquisition cost) established prices that are very similar to the Average Wholesale Price.” The report also retracted the above purported uncontested statement of fact at pages 32-34, noting that a comparison of AWPs to IMS data tends to “contradict HHS’ view that the AWP exceeded the price at which the pharmacist could obtain drugs by 15 to 18 percent.” It is also an undisputed fact that the report also noted that a 1979 study found that “for over half of the drugs examined, the 70th percentile of the IMS data was equal to AWP.” *Id.* at 34.

5.-6. Plaintiffs admit that the statement quoted appeared in the report. Plaintiffs dispute the relevance of the report. It is also an uncontested fact that the report noted that “efforts to control the [AWP] problem have not been successful.” *Id.* at 3. It is uncontested that the Report examined 3,468 purchases and found that 99.6 percent were made at prices averaging about “16 percent below AWP.” *Id.* It is undisputed that none of the drugs selected in the report were drugs at issue in the Track 1 case, and that none of the drugs were physician-administered drugs. It is also undisputed that the report makes no mention of the spreads in the ranges found by Dr. Hartman on the drugs at issue in this phase, or of the specific practices engaged in by drug companies to take advantage of the spread at the expense of Class Plaintiffs. *See* Plfs. Ex. 1 (Hartman Liability Report) to Declaration of Steve W. Berman in Response to Defendants’ Statement of Undisputed Facts (“Berman Decl.”) and Plaintiffs’ Response to Each Defendant’s

Motion for Summary Judgment. It is undisputed that Defendants have no evidence that any Class 1 plaintiff saw this report.

7. Plaintiffs admit that the statement appeared in the Federal Register. However, the full statement states “*some* state agencies” had questioned the use of Red Book and Blue Book. Further it is undisputed that nowhere in the report is any mention of the use of AWP by Defendants to increase market share, or of the size of the spreads of the Track 1 Defendants as reported by Dr. Hartman. *See* Berman Decl., Plfs. Ex. 1 (emphasis added). It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

8. Admitted. It is an undisputed fact that the report also notes that “[h]istorically the cost to Medicare has been based upon AWP.” It is submitted as uncontested fact that the recipient of this letter did not inform Mr. Newman of spreads on any of the Track 1 drugs in the magnitude as reported by Dr. Hartman or of similar drugs or of specific examples where drug manufacturers were marketing the spread.

9. Admitted.

10. Plaintiffs object to this proposed uncontested fact on the grounds that it is based on a hearsay statement by a purported HCFA attorney in a proceeding in Louisiana, reported in a partially provided transcript. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

11. Same objection as in ¶ 10. Further, it is uncontested that the transcript in context refers only to oral drugs and the transcript notes that the undersecretary meant that AWP, if used, must be used with a “reasonable discount,” *i.e.*, those discounts being given by wholesalers to

pharmacists, to arrive at an acceptable AWP (p. 160). It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

12. Plaintiffs object to this purported fact based on relevancy and hearsay.

13. Admitted. It is also uncontested that some manufacturers and trade organizations resisted proposed changes to AWP as a Medicare reimbursement benchmark. It is also an undisputed fact that the document does not contain any stated discrepancy between AWP and acquisition cost or refer to the marketing of the spread by drug companies.

14. Admitted. However, it is an undisputed fact that the report also states:

Finding 5: Prescription drug manufacturers have opted to expand their market by charging penthouse prices to compensate for the poverty of their innovation over the past decade.

- Unlike previous decades, during the 1980s drug manufacturers have been unable to expand their markets significantly by inventing new drugs for ailments lacking safe or effective treatment.

From 1980 through 1987 the volume of drugs used, and complexity of the mix of drugs used, changed little. Only 3% of the increase in total spending on prescription drugs was due to increased use of drugs by the public, according to analysis by researchers at the congressional Office of Technology Assessment (OTA) (see Appendix E). The same analysis concluded higher prices accounted for 97% of increased spending for prescription drugs from 1980-1987.

Analysis by the Congressional Budget Office, based on new data from the Department of Health and Human Services, confirms that drug prices – rather than increased used of drugs – are the primary force behind rapidly rising expenditures by the elderly for prescription drugs during the decade of the 1980s.

* * *

Finding 2: There are two markets in the United States for most big-selling prescription drugs: a price-competitive market characterized by deep discounts off the published list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs.

* * *

- The State of Kansas Medicaid program embarked on a program similar to DVA's three years ago, saving a few hundred thousand dollars per year....

Kansas Medicaid administrators estimate the State's taxpayers could save up to an additional \$500,000/year if manufacturers of the four currently marketed anti-ulcer drugs known as "82 antagonists" would respond to offers with bids.

Kansas officials believe State and federal governments could save hundreds of millions of dollars if Congress were to put into place a national bidding and negotiating program under the Medicaid program.

* * *

Finding 8: Actions by insurers and Medicaid progress to reduce drug costs by cutting pharmacy reimbursement have hurt pharmacies but have had little effect on prescription drug prices.

- In response to rising drug costs, insurers and Medicaid programs have sought to limit the size of reimbursement increases paid to pharmacists in recent years.

State laws and insurer policies generally recognize the manufacturer's published AWP as the reimbursable amount for the drug products itself, but there is no equivalent mechanism for identifying increases in pharmacist salaries and overhead.

The combined effect of rapidly rising wholesale prescription drug prices paid by pharmacists, and reimbursement limits imposed by insurers and Medicaid, are hurting pharmacists' profitability (see Appendices K and L).

It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

15. Admitted. In addition, it is undisputed that the report states: "Overall selling price would be about 12 percent off AWP...."

16. Plaintiffs object to the use of this exhibit, it is not a fact, rather it is an advocacy statement submitted in a brief before the Fifth Circuit. It is also rank hearsay, and irrelevant. It is

also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

17. Admitted, though the decision contains the following findings:

In June 1984, the Office of Inspector General published a lengthy report of an audit of pharmacy drug purchases in six states. The report found that 99.6% of these purchases were made at prices averaging approximately 15.93% below AWP.

In 1985, HCFA attempted briefly to enforce a uniform requirement that AWP be reduced by 10.5%, although this requirement was not in the regulations. The National Association of Chain Drug Stores, the National Association of Retail Druggists, and others sought declaratory and injunctive relief in federal district court against the enforcement of this requirement.

It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

18. Admitted.

19. Admitted. The report also states:

Generally, carriers base payments for the drug ... using one of the wholesale price guides such as Red Book. (p. 25.)

Medicaid policy, since the beginning of the Medicare Program, has been to base payment... on the estimated costs. *Id.*

20. Admitted.

21. Admit that the document is what it purports to be, but object on the grounds of relevancy and hearsay. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

22. Admit that the document is what it purports to be, but object on the grounds of relevancy and hearsay. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

23. Admitted. However the statement as quoted is incomplete and misleading. The same sentence quoted states that other drugs, *i.e.*, non multi-source were not discounted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

24. Admitted.

25. Admitted.

26. Denied.

27. Admitted. It is uncontested that this report did not reflect discounts greater than 20 percent less than AWP. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

28. Admitted. Plaintiffs counter-designate that the report also states that: “Our review was limited to a small judgmental sample of patients and physicians;” that only five physicians were surveyed (p. 4 & App. I); that “[t]he conclusions reached may not apply in all cases” (p. 11); and that a recommendation was made to conduct a broader survey “to assure widespread applicability” (p. 11). It is also undisputed that HCFA disagreed with one of the recommendations because “they lack assurance that a substantial number of physicians can obtain drugs at the lowest price available,” *see* pp. 12-13, and that HCFA generally believed that it required additional information (p. 3). It is also uncontested that the authors of this report discussed the spread between AWP and acquisition cost and that the report does not disclose the full extent of such spreads as reported by Dr. Hartman. *See* Berman Decl. Supporting Plaintiffs’ Motion for Partial Summary Judgment, Plfs. Ex. 1. Further, each of the Track 1 Defendants were aware of this report. Further, BMS was aware that it reported a spread of 12% and 17% for Bleomycin (App. III) while the real spread was far in excess, and a spread of 17% to 18% for Etoposide, which

had a real spread of 173% to 500%. *See* Berman Decl., Plfs. Ex. 1 at G.2.a. Further, it is uncontested that all of the Track 1 Defendants were aware of Medicare's use of AWP as a reimbursement benchmark. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

29. Admitted. As noted above, it is undisputed that Defendants were aware of Appendix III and were aware that the actual discounts on the published drugs were in excess of those in the Appendix. *See* Berman Decl., Plfs. Ex. 1 at G. It is undisputed that at the time of this report Defendants made no effort to publish the real spreads or to correct the reported AWP's for these drugs. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

30. Exhibit 27 as provided to Plaintiffs is not a March 1997 Fact Sheet but is a combination of reports. The attached March 10, 1993 report focuses on retail drugs not physician-administered drugs. Further, the report noted that "results of this study cannot be projected statewide." It is uncontested that none of the drugs discussed are Part B covered. Appendix I further notes that HCFA's policy was based on evidence that pharmacies purchased drugs that were, on average, about 16 percent below AWP. It is further an uncontested fact that the Track 1 drugs at issue were not only not identified in this report but in addition the fact the spreads on these drugs exceed 16% was not reported. *See* Berman Decl., Plfs. Ex. 1. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

31. Admitted.

32. Admitted.

33. Admitted.

34. Admitted.

35. Disputed and objected to as hearsay, and irrelevant.

36. Admitted. The report also states that “Medicare presently pays for most prescription drugs based on AWP.” It is undisputed that each Defendant was aware of this. It is further undisputed that an attachment to the report states that “through statistical sampling, AWP exceeding invoice prices by 17.5% for brand name drugs and 41.4% for generics.” It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

37. Admitted.

38. Admitted. It is also undisputed that the report also states that “Buying groups were able to offer lower prices ... because they negotiate prices directly with drug manufacturers ...” (p. 5.). It is uncontested that Schering is a manufacturer of albuterol sulfate. There is nothing in this report that indicates Schering’s spreads on albuterol exceeded 500%. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

39. Admitted. It is undisputed that the letter also directs this Blue Cross/Blue Shield to hold a claim on a new drug until “an AWP can be determined. You also asked if you could request an invoice if you believe that AWP was inflated. Under no circumstances should you be requesting invoices to determine pricing for drugs.” It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

40. Admitted as to what the document says; however, the purported fact is based on hearsay. To the extent it is admitted, the following are additional undisputed facts. The article also reports:

The high prices on generic drugs have led investigators to seek the source of the published AWP. Back in 1992, major drug manufacturers told the inspector general's office that the Red Book, not the manufacturers, determined the AWP. But Red Book officials blamed the manufacturers.

* * *

Phil Southerd, associate product manager of the Red Book, says it publishes prices that are faxed right from the manufacturers "They're not our prices," he insists.

Ed Edelstein, Blue Book editor, says that, while some brand-name firms don't give him prices, generic firms do. "The AWP is the manufacturer's suggested wholesale price," he says "It's our editorial policy to go along with that."

* * *

A maker of generic inhalants gives a different answer, but off the record. "The AWP typically originate with the manufacturer."

The article understated the discounts off AWP. Etoposide is reported at 75% off AWP, the real spread was in ranges of 173% to over 900%. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

41. Plaintiffs object to this asserted fact based on relevancy and hearsay.

42. Denied. The report is hearsay, and not relevant in that Defendants have failed to show that any class member was aware of this document or had access to it, since it was under seal.

43. Admitted. However, under F.R.E. 106, the sentence deleted from the quotation should be added: "The HHS Inspector General estimates that Medicare currently pays 15 to 30 percent more because the physician is marking up the drug when the manufacturer charges the patient less than the average wholesale price." Each of the manufacturers had spreads in excess of 30% at time for each drug at issue in Phase 1. Berman Decl., Plfs. Ex. 1. It is also an undisputed

fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

44. Admitted. It is also an undisputed fact that the same report at page 1 noted that the national average discount is commonly “about ten percent” and that the sampling produced a “national average of 18.3% below AWP.” It is undisputed that the report also contained the following passage, each of which contains undisputed facts:

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist’s usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist’s usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less a discount percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the Red Book, Medispan, or the Blue Book – publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

It is undisputed that the report was in the possession of each of the Track 1 Defendants and each did not correct or disclose the true average discounts off AWP for their drugs. Berman Decl.,

Plfs. Ex. 1. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

45. Denied. The report as submitted to Plaintiffs is an incomplete compilation of pages.

46. Denied. The purported facts are based on hearsay and otherwise contained in a document that is not a business record. To the extent this document is considered, Plaintiffs counter designate as undisputed that (1) there is not evidence any class member received this document or the information in it; (2) AstraZeneca did not supply actual spread information concerning Zoladex; or (3) correct in any fashion the then-current AWP's for Zoladex. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

47. Admitted. It is also an undisputed fact that each of the moving Defendants directly or indirectly supported adoption of this law and, prior to its adoption, made no effort to disclose to Congress the true spreads.

48. Plaintiffs dispute the relevancy of this offered fact. If admitted, plaintiffs counter designate as an undisputed fact that prior to this proposed law none of the moving Defendants disclosed their spreads on their drugs or their spread marketing practices.

49. Admitted. However, the reference below is misleading as on page 8, it is an undisputed fact that the reference to 900 percent more than the average price is to "one drug," with the J Code 50640. It is also undisputed that none of the J Codes at issue here are referred to in the report, and that none of the Defendants disclosed to OIG the actual spreads on the Track 1 drugs at issue. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

50. Admitted. It is also undisputed that each of the Defendants were aware of the spread on their drugs and did nothing to correct the accuracy to AWP's which they caused to be published.

51. Plaintiffs dispute the relevancy of this purported fact.

52. Admitted. It is also undisputed that the transmittal also states that "drugs and biologicals be paid at the lower of the billed charge or 95 percent of the Average Wholesale Price ("AWP") as described below." Further the instructions provide that the source of the AWP are sources such as "Red Book, Blue Book or Medispan."

53. Plaintiffs dispute the relevancy of this fact.

54. Plaintiffs dispute the relevancy of this fact.

55. Plaintiffs dispute the relevancy of this fact.

56. Plaintiffs dispute the relevancy of this fact.

57. Plaintiffs dispute the relevancy of this fact.

58. Plaintiffs dispute the relevancy of this fact.

59. Admitted. It is also an undisputed fact that the Track 1 Defendants who manufactured albuterol sulfate were aware of this report, and aware of the published AWP's for this drug, and did not disclose to OIG the true spread between AWP and acquisition cost. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

60. Admitted. It is also undisputed that each of the Defendants was aware of this section of the Federal Register and each did not disclose to the government true spreads. For example, AstraZeneca did not disclose the fact that the spread on Zoladex in 1996-1998 was 43% to 133% on NDC 00310096036, and 50% to 154% on NDC 00310096130. Berman Decl., Plfs.

Ex. 1 at C.1. BMS did not disclose at this time its spreads. For example, Blenoxane NDC 00015301020 spreads were in excess of 70% in 1998; and Vepesid NDC 0015306120 had spreads in excess of 500% in 1997 and 200% in 1998. *Id.* at G.2.c. GSK did not disclose spreads on Zofran NDC 00173046100 that were in excess of 65% at this time. *Id.* at G.3.c. J&J did not disclose that its spreads on Procrit at this time exceeded 25% for most NDCs. *Id.* at G.4. Schering did not disclose that spreads on Abuterol exceeded 200% and were as high as 400%. *Id.* at G.5.c. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

61. Admitted.

62. Admitted.

63. Plaintiffs dispute the relevancy of this fact.

64. Plaintiffs dispute the relevancy of this fact.

65. Plaintiffs dispute the relevancy of this fact.

66. Plaintiffs dispute the relevancy of this fact.

67. Plaintiffs dispute the relevancy of this fact. It is undisputed that Schering was aware of this report and was aware that the spread between AWP for albuterol and ASP was in excess of 200%. Berman Decl., Plfs. Ex. 1 at G.5.

68. Plaintiffs object to this fact on the grounds it is based on hearsay.

69. Plaintiffs object to this purported fact on the grounds that it is based on hearsay. If this fact is admitted, then Plaintiffs counter designate as undisputed the following:

In recent weeks, we have heard from many concerned constituents, including oncologists, hospitals, and chemotherapy patients and their families, about the administrative initiative by the Department of Health and Human Services (HHS) to change the Medicare reimbursement structure for many cancer drugs. Because we are concerned that this new initiative could affect both the quality

and quantity of care that Medicare cancer patients receive, we urge you to carefully reconsider your proposed change.

* * *

We understand HHS' concerns that the reimbursement rate for many drugs may exceed the actual acquisition costs. According to our oncologists, however, this margin pays for wastage, spillage, and administrative costs – including the extra costs of skilled personnel, inventory, and preparation – for which they say they are inadequately reimbursed. They tell us that, although Medicare makes a payment for chemotherapy administration services, the payment is only a fraction of what is necessary to cover their expenses, and they use payment amounts for drugs to help cover these expenses.

69(a). It is an undisputed fact that at the time this letter was sent each of the Defendants were aware that the spreads they offered physicians (*see* Berman Decl., Plfs. Ex. 1) vastly exceed a physician's costs and were marketed as a profit maker for the doctors. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

70. Admitted. It is an undisputed fact that at the time this letter was sent each of the Defendants was aware that the spreads they offered physicians (*see* Berman Decl., Plfs. Ex. 1) vastly exceed a physician's costs and were marketed as a profit maker for the doctors. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

71. Admitted. It is also an undisputed fact that at the time of this report, each of the Defendants was aware of published AWP's that exceeded their ASP for their drugs. *See* Berman Decl., Plfs. Ex. 1. None of the companies publicly disclosed the amounts by which average acquisition costs exceeded AWP. *Id.* Further, each of the Defendants continued to take steps to market to doctors and prescribers of the spread. *See* Declaration of Steve W. Berman in

Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

72. Admitted. It is also an undisputed fact that at the time of this report, each of the Defendants was aware of published AWP's that exceeded their ASP for their drugs. *See* Berman Decl., Plfs. Ex. 1. None of the companies publicly disclosed the amounts by which average acquisition costs exceeded AWP. *Id.* Further, each of the Defendants continued to take steps to market to doctors and prescribers of the spread. *See* Declaration of Steve W. Berman in Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

73. Admitted. It is also an undisputed fact that at the time of this report, each of the Defendants was aware of published AWP's that exceeded their ASP for their drugs. *See* Berman Decl., Plfs. Ex. 1. None of the companies publicly disclosed the amounts by which average acquisition costs exceeded AWP. *Id.* Further, each of the Defendants continued to take steps to market to doctors and prescribers of the spread. *See* Declaration of Steve W. Berman in Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

74. Admitted. It is also an undisputed fact that at the time of this report, each of the Defendants was aware of published AWP's that exceeded their ASP for their drugs. *See* Berman Decl., Plfs. Ex. 1. None of the companies publicly disclosed the amounts by which average acquisition costs exceeded AWP. *Id.* Further, each of the Defendants continued to take steps to market to doctors and prescribers of the spread. *See* Declaration of Steve W. Berman in Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

75. Admitted. It is also an undisputed fact that at the time of this report, each of the Defendants was aware of published AWP's that exceeded their ASP for their drugs. *See* Berman Decl, Plfs. Ex. 1. None of the companies publicly disclosed the amounts by which average acquisition costs exceeded AWP. *Id.* Further, each of the Defendants continued to take steps to market to doctors and prescribers of the spread. *See* Declaration of Steve W. Berman in Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

76. Admitted. It is also admitted and counter designated as an undisputed fact that the report at page 4 states, "[f]or **most** physician-administered drugs, the overall discount ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 percent and 86 percent." The drug at 86 percent was albuterol. It is undisputed that each Defendant was aware of this report and of the fact that their drugs had discounts exceeding 30% and, in the case of albuterol, exceeding 500%. Berman Decl., Plfs. Ex. 1. It is also counter designated that the report found that determining actual acquisition cost is "complicated" due to the practices of the manufacturer. *Id.* It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

77. Admitted. It is also admitted and counter designated as an undisputed fact that the report at page 4 states, "[f]or **most** physician-administered drugs, the overall discount ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 percent and 86 percent." The drug at 86 percent was albuterol. It is undisputed that each Defendant was aware of this report and of the fact that their drugs had discounts exceeding 30% and, in the case of albuterol, exceeding 500%. Berman Decl., Plfs. Ex. 1. It is also counter designated that the report found that determining actual acquisition cost is "complicated" due to the practices of the

manufacturer. Further, none of the drugs at issue here had discounts discussed except Epoetin, whose discount is understated (p. 12). *See* Berman Decl., Plfs. Ex. 1. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

78. Admitted. However, it is also undisputed that at p. 88 of Ex. 73, Mr. Scully stated as follows:

MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers discounts that reduce the actual amount that the physician or provider actually pays for the drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the Red Book. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices creates a situation where a manufacturer can, for certain drugs, increase the reported AWP and, in turn, offer physicians a deeper discount.

The Committee, CMS, the Department's Office of the Inspector General ("IG"), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. TH IG has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and like publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. By offering physicians and providers deep discounts compared to the price they could bill Medicare, the drug manufacturers are able to use profit margin to manipulate physicians and providers to use their products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in a way that costs beneficiaries and the program far more than it should.

Each Defendant was aware of the foregoing and made no effort to correct the AWP's for the drugs at issue and continued to emphasize the profits to be made based on the spread. *See* Declaration of Steve W. Berman in Opposition to Each Defendant's Individual Motion. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

79. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

80. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

81. Denied. Plaintiffs object to this fact as it is based on hearsay.

82. Denied as the fact is based on an incomplete document and is hearsay.

83. Admitted, however, it is also undisputed that the sentence prior to the quotation states that "Manufacturers report AWP's to organization that publish them." *See* 00219. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

84. Admitted. It is further undisputed that none of the fast track Defendants disclosed their spreads, that the spreads vastly exceeded anything in the reference report with respect to brand name drugs or albuterol and that after this report each Defendant was aware of the use by Medicare of AWP's for their drugs. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

85. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

86. Admitted. However, it is undisputed that the report states:

What is AWP?

- Can be thought of as manufacturer's suggested list price
- Drug pricing information is proprietary so AWP (which is public) has been used as a benchmark in negotiations by the industry
- AWP has never been defined in statute or regulation

Drugs are available at prices well below AWP

- GAO found catalogue prices for drugs ranged from 13% to 86% below AWP
 - Medicare paid about \$1 billion dollars above acquisition costs in 2000
 - These figures do not include rebates and other discounts widely available to providers
 - In some cases, beneficiary coinsurance was higher than acquisition costs

Current system provides incentives for higher prices

- Differences between AWP and acquisition costs are highest for products available from more than one source
 - 85% and 78% discounts for albuterol and ipratropium bromide, most commonly billed pharmacy supplier drugs
 - Large spreads for single source drugs viewed as interchangeable by physicians

It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

86(a) It is also undisputed that at the time of this testimony each Defendant (1) knew AWP's with respect to its Part B covered drugs were used as a basis for reimbursement, (2) had not disclosed the true spreads on its drugs, and (3) that the spread provided a profit to a physician. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

87. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information. It is also undisputed that the report, at pages 156-57, also states:

The phenomenon of a gap between AWP and actual wholesale prices is not limited to Medicare.... ***Thus the actual price charged to any one customer is a closely guarded trade secret.*** Under these circumstances, AWP is a benchmark for negotiations. For example, a typical contract between a pharmacy benefit manager and a pharmacy might call for reimbursement for drugs according to a formula based on AWP minus 13 percent plus a dispensing fee. However, the Medicare payment method has resulted in increasing gaps between AWP and provider purchase prices.

* * *

Incentives for increasing AWP

In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers. Although the manufacturer's profit per dose will not increase with the rise in the list price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor. At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of \$740, was sold to physicians for \$7.50 per dose. The beneficiary's copayment (about \$150) was about 20 times providers' acquisition cost.

Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy (see text box, p. 158). They leave the AWP at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share.

On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers. If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In

other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products. It is too soon to know how these guidelines will affect pharmaceutical company marketing practices.

88. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information. It is also undisputed that none of the Defendants (1) disclosed to Congress the true spread, or (2) took any step to publish the ASP or correct the AWP.

89. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

90. Admitted. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

91. Plaintiffs object to this fact and its relevancy and on hearsay grounds. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

92. Denied, also based on hearsay and objected to as irrelevant. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

93. Denied. Ex. 86 at the cited paragraphs does not so state. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

94. Denied, as the purported fact snippets are out of context. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

95. Denied, as the purported fact snippets are out of context. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

96. Denied as Ex. 86 as provided is indecipherable. It is also an undisputed fact that Defendants offer no evidence that any Class 1 plaintiff or class member was aware of this information.

97. Denied.

98. Denied, and/or taken out of context. Counsel is free to argue from the report/testimony, however, as cited it is incomplete and misleading.

99. Denied, as this is an incomplete and improper selection of snippets. It is also undisputed at the deposition that the Defendants did not ask the witness if he was (1) aware of the magnitude of spreads for their drugs, or (2) aware of any practices they engaged in designed to market the spread.

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By /s/ Steve W. Berman
Thomas M. Sobol (BBO#471770)
Edward Notargiacomo (BBO#567636)
Hagens Berman Sobol Shapiro LLP
One Main Street, 4th Floor
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

LIAISON COUNSEL

Steve W. Berman
Sean R. Matt
Hagens Berman Sobol Shapiro LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Elizabeth Fegan
Hagens Berman Sobol Shapiro LLP
60 W. Randolph Street, Suite 200
Chicago, IL 60601
Telephone: (312) 762-9235
Facsimile: (312) 762-9286

Eugene A. Spector
Jeffrey Kodroff
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

Kenneth A. Wexler
Jennifer Fountain Connolly
The Wexler Firm LLP
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

Marc H. Edelson
Allan Hoffman
Edelson & Associates LLC
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Shanin Specter
Donald E. Haviland, Jr.
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
Facsimile: (215) 772-1359
Telephone: (215) 772-1000

**CO-LEAD COUNSEL FOR
PLAINTIFFS**

CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on April 7, 2006, I caused copies of **RESPONSE OF CLASS PLAINTIFFS' TO STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF TRACK 1 DEFENDANTS' MOTION FOR SUMMARY JUDGMENT** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

Steve W. Berman